

***** List of reported SAE's *****

-> group == Arm1: Experimental (1 arm only)

ssoccd	SOC code	aeterm	affected	exposed	occurrences	occurrel	fatality	fatalrel
	(syncope)-> anemia		1	85	1	1	.	.
Blood and lymphatic system disorders	Febrile neutropenia		3	85	3	3	.	.
Blood and lymphatic system disorders	Neutropenic fever		4	85	5	5	.	.
Cardiac disorders	AVNTR		1	85	1	1	.	.
Cardiac disorders	Decompensatio cordis		2	85	2	1	.	.
Cardiac disorders	Tachycardia		1	85	1	.	.	.
Gastrointestinal disorders	Abdominal pain		2	85	2	.	.	.
Gastrointestinal disorders	Colitis		1	85	1	1	.	.
Gastrointestinal disorders	Constipation		2	85	2	.	.	.
Gastrointestinal disorders	Diarrhea		1	85	1	1	.	.
Gastrointestinal disorders	Diarrhea and vomiting		1	85	1	1	.	.
Gastrointestinal disorders	Gastric perforation		1	85	1	1	.	.
Gastrointestinal disorders	Gastrointestinal disorder		1	85	1	1	.	.
Gastrointestinal disorders	Ileus		1	85	1	.	.	.
Gastrointestinal disorders	Nausea/Vomiting		1	85	1	1	.	.
Gastrointestinal disorders	Passage problems gastrointestinal		1	85	1	.	.	.
Gastrointestinal disorders	Vomiting		1	85	2	2	.	.
General disorders and administration site conditions	Death NOS		1	85	1	.	1	.
General disorders and administration site conditions	Fever		2	85	2	1	.	.
General disorders and administration site conditions	Fever after chemotherapy		1	85	1	1	.	.
General disorders and administration site conditions	Malaise		3	85	3	2	.	.
General disorders and administration site conditions	Mucositis		1	85	1	1	.	.
General disorders and administration site conditions	Weakness		1	85	1	.	.	.
Infections and infestations	Bronchial infection		1	85	1	.	.	.
Infections and infestations	Catheter sepsis		1	85	1	1	.	.
Infections and infestations	Erysipelas infection		1	85	1	1	.	.
Infections and infestations	Gastro-enteritis		2	85	2	1	.	.
Infections and infestations	Infection Haemophilus influenzae		1	85	1	1	.	.
Infections and infestations	Lung infection		1	85	1	.	.	.
Infections and infestations	Pleural empyema		1	85	1	1	.	.
Infections and infestations	Pneumonia		1	85	1	1	.	.
Infections and infestations	Pneumosepsis at neutropenia patient		1	85	1	1	.	.
Infections and infestations	Sigmoid diverticulitis		1	85	1	1	.	.
Infections and infestations	Upper respiratory infection		1	85	1	1	.	.
Infections and infestations	Urinary tract infection		2	85	2	2	.	.
Infections and infestations	Urosepsis		1	85	1	1	.	.
Infections and infestations	Viral infection		1	85	1	1	.	.
Injury, poisoning and procedural complications	Hip fracture		1	85	1	.	.	.
Investigations	GGT increased		1	85	1	.	.	.
Metabolism and nutrition disorders	Anorexia		1	85	1	1	.	.
Musculoskeletal and connective tissue disorders	Osteoporosis		1	85	1	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	ALL		1	85	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenocarcinoma		1	85	1	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma		1	85	1	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung carcinoma		1	85	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant Neoplasm Lung NSCLC (SPM)		1	85	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	SPM: colon carcinoma		1	85	1	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Treatment related MDS		1	85	1	1	1	1
Nervous system disorders	Headache		1	85	1	.	.	.
Nervous system disorders	Headache (postfunctional)		1	85	1	.	.	.
Nervous system disorders	Hypoglossal nerve failure		1	85	1	.	.	.
Nervous system disorders	Neuropathic pain in left arm		1	85	1	.	.	.
Renal and urinary disorders	Kidney failure		1	85	1	.	.	.
Renal and urinary disorders	Renal disorder other: kidney stones		1	85	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Dyspnea		1	85	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism		1	85	1	1	.	.
Surgical and medical procedures	Removal of foreign object in right lung		1	85	1	.	.	.
Vascular disorders	Phlebitis left arm		1	85	1	.	.	.